UNITED STATES DISTRICT COURT FOR THE DISTRICT OF MASSACHUSETTS

IN RE: PHARMACEUTICAL INDUSTRY) MDL NO. 1456
AVERAGE WHOLESALE PRICE)
LITIGATION) CIVIL ACTION: 01-CV-12257-PBS) Subcategory Docket: 06-CV-11337-PBS
THIS DOCUMENT RELATES TO) Judge Patti B. Saris
U.S. ex rel. Ven-A-Care of the Florida Keys, Inc. v. Abbott Laboratories, Inc., et al., No. 06-CV-11337-PBS) Magistrate Judge Marianne B. Bowler)
)

ABBOTT LABORATORIES INC.'S RESPONSE TO THE UNITED STATES' RESPONSE TO THE COURT'S INSTRUCTION RELATING TO STATE MEDICAID CLAIMS DATA

INTRODUCTION

On January 27, 2010, this Court held oral argument on Defendants' spoliation motions. In reliance on oral representations by the Government during the hearing that were flatly inconsistent with information in its own files, the Court denied (without prejudice) Defendants' spoliation motions. This submission responds to the United States' recently filed Response to the Court's Instruction Relating to State Medicaid Claims Data (Dkt. No. 6898), and further clarifies the record relating to the spoliation of damages-related evidence. Because the Government recently abandoned its attempt to extrapolate damages for Medicare claims (*see* Dkt. No. 6897), this submission focuses upon the loss of Medicaid claims data.

While acknowledging that Defendants raised spoliation concerns over other categories of government documents, the Court's principal focus at this point in the litigation – in light of the recent *Daubert* hearing – was on damages evidence. With respect to other categories of government documents, the Court denied Defendants' motion without prejudice to raise spoliation issues at trial. (*See* Jan. 27, 2010 Hrg. at 22 ("So it's primarily at this point, anyway, a damages sanction that you're seeking?"), 53 ("Well, maybe you get an adverse inference at trial, I don't know, but at this point I don't know enough about why it matters. . . . I'd be speculating about prejudice. . . . I know what the prejudice is on the damage data. That I could have figured out. That's what I came in here thinking about, actually, because that's where the focus of so much of this has been.").)

The Government's recent pleading serves as an admission that there was no basis for its prior contention that "absolutely nothing . . . has been destroyed." (Jan. 27, 2010 Hrg. at 23.) To the contrary, the evidentiary record, discussed *infra*, shows a significant loss of relevant evidence, including Medicaid claims data and Medicare pricing arrays. The Government cannot escape the realities of this rampant spoliation through vague and incomplete representations about what was searched and what was lost, and remote speculation of what might still possibly exist (but that no one was able to locate). On this record, there should never have been any dispute that extensive evidence relating to damages has been lost. As Abbott has contended in its *Daubert* challenge, the Court should reject the Government's attempt to "fill the gaps" in the spoliated evidence of damages through unreliable expert testimony. *See United Med. Supply Co., Inc. v. United States*, 77 Fed. Cl. 257, 275 (2007); *see also Jones v. Hawley*, 255 F.R.D. 51, 54 (D.D.C. 2009).²

ARGUMENT

I. THE GOVERNMENT'S INACTION DID RESULT IN THE SIGNIFICANT LOSS OF STATE MEDICAID CLAIMS DATA.

A. The Government Could Have Preserved Medicaid Claims Data.

The Government's recent filing again asserts that it had no obligation to preserve claims data from the states. (Dkt. No. 6898 at n.1.) But the cases cited by the Government have nothing to do with the circumstances at issue here. In *Townsend v. American Insulated Panel Co.*, 174 F.R.D. 1 (D. Mass. 1997), the court held that a plaintiff injured by an electric shock from a walk-in freezer could not be held responsible for her employer's eventual dismantling of the freezer. The court found no "evidence that the plaintiff was at fault for the loss or destruction of the walk-in freezer." (*Id.* at 5.) Similarly, in *Friends for All Children, Inc. v. Lockheed Aircraft Corp.*, 587 F. Supp. 180, 189 (D. D.C.), *modified on reconsideration*, 593 F. Supp. 338

² The Government has also recently filed a Notice of Filing of Confidence Interval Calculations (Dkt. No. 6899). Abbott has submitted its expert's response to Dr. Duggan's fundamentally flawed confidence intervals in a separate pleading, filed concurrently herewith.

(D. D.C.), *aff'd*, 746 F.2d 816 (D.C. Cir. 1984), the court held that defendant *Lockheed Aircraft Corporation* could not be held responsible for the Air Force's (a third party) destruction of crash-related photographs and videotapes. (*Id.* at 189.)

The circumstances here, of course, are much different. Medicaid is a joint federal-state program and the federal government – as its own actions and recent filing confirm – does have the ability to control and preserve claims data maintained by the states. 42 U.S.C. § 1396a(6), 42; 42 C.F.R. § 447.333. 42 C.F.R. § 447.333 specifically requires state Medicaid agencies to "make available to HCFA, upon request, *data*, mathematical or statistical *computations*, comparisons, and any other *pertinent records* to support it findings and assurances" that its payments for drugs comply with federal financial participation requirements. (42 C.F.R. § 447.333(c) (emphasis added).) That regulation surely provides the Government the right to request basic claims data from the states. Indeed, the Government's recent pleading shows that it *did* successfully obtain claims data from numerous states for these cases. (Dkt. No. 6898 at 2-6.)

Moreover, the Government cannot dispute that manufacturers *specifically requested* the Government to take immediate steps to preserve relevant evidence from the states. (Dkt. No. 6097 at 4, Ex. Q.) Nor can the Government dispute that it has entered into "common interest agreements" with numerous states related to the prosecution of AWP-related claims. None of these circumstances existed in the cases relied upon by the Government.

Most telling is DOJ's letter of November 3, 2006 to the states, which DOJ withheld until the Court ordered its production during the hearing. That letter included the following directive:

In view of the pending litigation and likely discovery requests, we ask you to take measures to ensure the preservation of all documents, electronic data, and other information potentially relevant to subjects concerning state Medicaid payment for drugs. *This would include, without limitation, electronic claims data*; Medicaid rebate information; information regarding reimbursement policies or formulas; information concerning any knowledge of actual drug prices; communications with drug manufacturers, wholesalers and/or drug pricing publications regarding drug pricing and/or

drug reimbursement amounts; and any internal deliberations on how the state developed its definition of Estimated Acquisition Cost in its state Medicaid plan. We particularly request that you ask your records and data management representatives to freeze the routine destruction or deletion of such information.

(Ex. A at 1-2) (emphasis added).

None of these facts can be squared with the Government's suggestion that it had no control or ability to ask the states to preserve claims data and other relevant information. In sum, the Government *did* have "the right, authority, or practical ability" to obtain and preserve claims data from the states, *In re NTL Sec. Litig.*, 244 F.R.D. 179, 195 (S.D.N.Y.) (emphasis added), and its failure to do so in a timely manner *has* impacted what exists today.

B. The Government's Recent Filing Admits A Significant Loss of State Medicaid Claims Data During the 1991-2001 Damage Period.

The Court need look no further than the Government's recent filing on state claims data (Dkt. No. 6898) to see that – contrary to its assertions during the spoliation hearing – there *has* been a significant loss of state Medicaid claims data.³ Among other things, that pleading admits:

- Since late 2006, DOJ "made a least preliminary contact with *50 states* in an effort to obtain state data." (*Id.* at 4.)
- Despite those contacts, DOJ obtained (usually incomplete) data for the Abbott drugs from only 29 states. (*Id.* at 2-3.)⁴
- Of those 29 states, *only 5 states* (CT, IL, IA, MD & OH) produced data for the entire time period relevant to the Abbott case. (*Id.*)

³ In light of previous testimony and documents produced during discovery, the Government's contention during the hearing that "absolutely nothing . . . has been destroyed" (Jan. 27, 2010 Hrg. at 23) came as a bit of a surprise. For example, during his deposition, Dr. Duggan testified he directed DOJ to initiate calls with certain states and "acquire[] as much data as they could from states," and that "one factor" in his selection of what to include in his Medicaid "sample" was "just the availability of data, whether the state Medicaid agency or its contractor had the data." (Ex. B at 251-52.) (*See also* Ex. C at 147480, 82 (indicating additional years of data were not available from numerous states).)

⁴ The Government claims that "some states (for example, Oregon and Colorado) simply declined to produce any data to the United States," and that, "for some states," the "collection effort was limited or abandoned." (Dkt. No. 6898 at 4-5.) The Government's vague references to "some states" is not particularly helpful.

- Of the 29 states, 7 states (AR, GA, IN, MI, MN, NC & VA) produced data for *three years or less* of the relevant period. (*Id.*)
- At least 8 states affirmatively told DOJ they were *unable to produce* data for much of the relevant period. For example, Georgia, Michigan, Indiana, Virginia, and Oklahoma all informed DOJ that they could not produce data before 2000. (*Id.* at 5-6.) Mississippi was unable to produce any data. (*Id.*)

While the Government submits that, "[f]or other states, DOJ has been unable to make a final, conclusive determination regarding the extent of the archived data" (*id.* at 5), it cannot reasonably be disputed that gaps in many other states' productions are also attributable to the loss of data. Indeed, a document produced in connection with Dr. Duggan's original report (and marked during his deposition) indicates that additional data, beyond that already produced, was *not* available for numerous states (including Kentucky, Missouri, Louisiana, North Carolina, and Utah). (*See* Ex. C (see the "no" in the "More years possible" column at 147480, 82).)

In sum, the Government's failure to request that states preserve claims data undeniably *has* resulted in the widespread spoliation of claims data.⁵

⁵ Although it has abandoned Dr. Duggan's Medicare extrapolations (see Dkt. No. 6897), DOJ's assertions regarding the search for and availability of Medicare pricing arrays were similarly unfounded. Abbott was *not* told that a search of carrier files likely to have arrays "was never done based on the burden." (Jan. 27, 2010 Hrg. at 24.) To the contrary, DOJ told Abbott during discovery that it "certifies that Abbott's RFPs [which included a specific request for pricing arrays] were transmitted to all Carriers likely to have responsive information and they were directed, pursuant to their contracts to provide material in response thereto." (Ex. D (emphasis added); see also Ex. E (March 6, 2008 response letter from Abbott) (Abbott "will assume that the Government and its contractors have been diligent in their searches, and will have located and produced all array information that still exists by March 31, 2008"); Dec. 10, 2009 Hrg. at 94 (Duggan testimony at *Daubert* hearing: "arrays that could be obtained were obtained"). A document recently produced by DOJ in response to the Court's directive indicates that DOJ did not require carriers to search "offsite" files because pricing arrays were contained in "discrete drug files." (Ex. F at HHD927-0002.) Moreover, there can be no dispute that there has been a significant loss of pricing arrays. (See Ex. G at 48-49 (Cigna deposition: although it produced arrays from only 1997 forward, Cigna has "satisfy[ied] [it]self that [it] produced all documents that were available"); Ex. H at 42-43 (AdminiStar deposition: with the exception of one J-Code, "AdminiStar has no array records or other applicable records regarding reimbursement rates" from 1991-2001); Ex. I at 100-02, 105-07 (Palmetto Part B deposition: "could not locate" arrays for 1991-99 time period" despite searching "electronic network files" and "hard copy documentation").)

Dated: February 24, 2010 Respectfully submitted,

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CERTIFICATE OF SERVICE

I, David S. Torborg, an attorney, hereby certify that I caused a true and correct copy of the foregoing to be served on all counsel of record electronically by causing same to be posted via LexisNexis, this 24th day of February, 2010.

/s/ David S. Torborg
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